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10/727,151

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David K. Swanson

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Vista IP Law Group LLP
2040 MAIN STREET, 9TH FLOOR
IRVINE, CA 92614

EXAMINER

ROANE, AARON F

ART UNIT

PAPER NUMBER

3739

MAIL DATE

DELIVERY MODE

06/12/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/727,151 | Applicant(s) SWANSON, DAVID K. | |
| | Examiner AARON ROANE | Art Unit 3739 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14, 17, 19, 20 and 32-42 is/are pending in the application.
- 4a) Of the above claim(s) 38 and 39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14, 17, 19, 20, 32-37 and 40-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Withdrawal of Allowable Subject Matter

The indicated allowability of claims 32-37, 40 and 41 are withdrawn in view of the reevaluated reference(s) to Gadsby et al. (USPN 5,309,909) in view of Rau (USPN 4,685,466) or Daddona et al. (USPN 6,091,975). Rejections based on the newly cited reference(s) follow.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 14, 17, 19, 20, 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gadsby et al. (USPN 5,309,909) in view of Rau (USPN 4,685,466).

Regarding claims 14 and 32, Gadsby et al. disclose a surgical apparatus for use with a tissue structure, comprising: a tissue stimulation electrode(s) (18 and/or collection of 18) having a diameter of about 0.5mm to 1.0mm, wherein a size of the tissue stimulation element is too small to form a transmural myocardial lesion, see col. 3, line 53 through col. 6, line 29 and figures 1-4. Gadsby et al. fail to disclose a means, associated with the tissue stimulation element, for securing the surgical apparatus to the tissue structure by engaging a single side of the tissue structure and pressing the stimulation element against the single side of the tissue structure. Rau disclose a electrode measuring device comprising a cup (2 and alternate/equivalents in other embodiments) and sharp pointed needle electrode(s) (1 and alternate/equivalents in other embodiments) and teach providing the device with a suction means (vacuum line 4) in order to secure the surgical apparatus to the tissue structure by engaging a single side of the tissue structure and pressing the stimulation element against the single side of the tissue structure, see col. 4-5 and figures 1-7. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Gadsby et al., as taught by Rau, to provide the device with a suction means (vacuum line 4) in order to secure the surgical apparatus to the tissue structure by engaging a single side of the tissue structure and pressing the stimulation element against the single side of the tissue structure as an alternative to pressing the device against the skin by hand.

Regarding claims 17 and 33, Gadsby et al. disclose a surgical apparatus for use with a tissue structure, comprising: a tissue stimulation electrode(s) (18 and/or collection of 18) having a diameter of about 0.5mm to 1.0mm, wherein a size of the tissue stimulation element is too small to form a transmural myocardial lesion, see col. 3, line 53 through col. 6, line 29 and figures 1-4. Gadsby et al. fail to disclose an anchor, associated with the tissue stimulation element, the anchor being configured to secure the surgical apparatus to the tissue structure by piercing the tissue and pressing the stimulation element against the tissue. Rau disclose an electrode measuring device comprising sharp pointed needle electrode(s) (1 and alternate/equivalents in other embodiments) and teach providing the device with an anchor in the form of a suction cup (2 and vacuum line 4) in order to press the electrodes against the tissue, see col. 4-5 and figures 1-7. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Gadsby et al., as taught by Rau, to provide an anchor in order to press the electrodes against the tissue and pierce the tissue.

Regarding claims 19 and 20, both Gadsby et al. and Rau further disclose a flexible carrier (flexible 16 of Gadsby et al. and flexible portion of 2 in Rau), wherein the flexible carrier is non-linear when in a relaxed state.

Claims 34-37 and 40-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gadsby et al. (USPN 5,309,909) in view of Daddona et al. (USPN 6,091,975).

Regarding claim 34, Gadsby et al. disclose a surgical apparatus for use with a tissue surface, comprising: first and second tissue stimulation electrodes (any two farthest separated 1 electrode numbered 18); a flexible carrier (14) movable between an unstressed state and a deflected and stressed state and including a first end portion (adjacent and closest to 36) that carries the first tissue stimulation element, a second end portion (farthest from 36) that carries the second tissue stimulation element, and a curved interior portion located between the first and second end portions and configured such that the curved interior portion will be in spaced relation to the tissue surface when the end portions are in contact with the tissue surface and the carrier is in the unstressed state, see col. 3, line 53 through col. 6, line 29 and figures 1-4. Gadsby et al. fail to disclose a tissue engagement device carried by the curved interior portion of the carrier between the first and second tissue stimulation elements and configured to secure the carrier to the tissue surface in the deflected and stressed state. Daddona et al. disclose a electrical device for the skin and teach providing the device with a tissue engagement device in the form of a collection of “microprotrusion” barbs (jagged additions to some, i.e. every third electrode 4) in order “to maximize the electrode area while maintaining the small protrusion size necessary for minimally invasive operation” and further secure the device to the

skin and as an alternative to pressing the device against the skin by hand, see col. 2, line 18-26 and col. 2 and 3 and figures 1-4. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Gadsby et al., as taught by Daddona et al., to provide the device with a tissue engagement device in the form of a collection of “microprotrusion” barbs in order “to maximize the electrode area while maintaining the small protrusion size necessary for minimally invasive operation” and further secure the device to the skin and as an alternative to pressing the device against the skin by hand.

Regarding claim 35, Gadsby et al. further disclose the carrier is configured to press the tissue stimulation element against the tissue surface when in the deflected and stressed state.

Regarding claims 36, 37 and 40-42, Gadsby et al. in view of Daddona et al. disclose the claimed invention.

Response to Amendment

Upon further review and reconsideration, the previously objected and/or allowable subject matter has been found not to distinguish over the prior art. In other words the allowable (and/or objected to) subject matter has been rejected upon

reevaluation of the prior art Gadsby et al. (USPN 5,309,909) in view of Rau (USPN 4,685,466) or Daddona et al. (USPN 6,091,975). Rejections to the pending claims have been presented above. This action is made non-final due to the new grounds of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON ROANE whose telephone number is (571)272-4771. The examiner can normally be reached on Monday-Friday 5:30AM-3PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/AARON ROANE/
Examiner, Art Unit 3739

/Henry M. Johnson, III/
Primary Examiner, Art Unit 3739